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cc

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/467,160 | 12/20/99 | PELUS | L P50161-X1-D1 |

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| EXAMINER | |
|---|---|
| SEHARASEYON, J | |
| ART UNIT | PAPER NUMBER |
| 1647 | 11 |

DATE MAILED: 06/28/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/467,160 | PELUS ET AL. | |
| | Examiner | Art Unit | |
| | Jegatheesan Seharaseyon | 1647 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136.(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *36-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
18) ☒ Interview Summary (PTO-413) Paper No(s). 8 .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

## DETAILED ACTION

**1.** Applicant's election without traverse of Group III, claims 36-39 in Paper No: 9 is acknowledged. Claims 36-39 are pending and are rejected.

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

4. The declaration is defective. The declaration is defective because it does not properly identify the specification to which it is directed. In addition, the declaration states that the specification is "attached hereto." However, the declaration and specification were not filed on the same day. A new declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 36-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification is insufficient to enable one skilled in the art to practice the claimed invention without an undue amount of experimentation. There is no *in vitro* or *in vivo* data which is indicative of the claimed invention of treating of viral, fungal and

bacterial infections. The assays described in example 7(last paragraph) and example 8 of the specification (pages: 34-35) indicate a biological activity to gro-β and gro-γ proteins in the presence of colony stimulating factor (CSF). However, it does not describe the activity of the polypeptide consisting of amino acids 5-73 of SEQ ID No. 3 alone. There is no indication that the assay accurately reflects the effect of the polypeptide consisting of amino acids 5-73 of SEQ ID No. 3 in the dynamic environment of a living body. This disclosure of the biological activity is insufficient to teach one of skilled in the art how to use the claimed peptide in therapeutic methods.

Applicant has not disclosed how to use the claimed invention to treat the infections of the subjects. There is insufficient evidence of the invention with respect to the *in vivo* operability of the claimed invention. In addition, there is no guidance provided in choosing the treatment regimen with therapeutically effective amount for administering to the subjects. Applicant recites a broad, arbitrary range with no evidence of the amount necessary to achieve the desired effect in subjects with viral, fungal and bacterial infections (page 26, line 34 to page 27, line 7).

Pharmaceutical therapies are unpredictable for the following reasons; (1) the proteins may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half life protein; (2) the protein may otherwise not reach the target area because, for example, the protein may not be able to cross the mucosa; (3) other functional properties, known or unknown, may make the protein unsuitable for *in vivo use*, i.e. may produce adverse side effects prohibitive to the use of such treatment. The specification lacks an art

recognized model which would indicate the therapeutic effectiveness of the claimed peptide.

Since applicant has not provided any working examples of the efficacy of using amino acids 5-73 of SEQ ID No: 3 in treating subjects with viral, fungal and bacterial infections, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention.

Given the breadth of claims 36-39, in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention for treating of viral, fungal and bacterial infections. In addition, due to the lack of established protocols for effective cytokine therapies, undue experimentation would be required to practice the claimed invention and would have little expectation of success.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6a. Claim 36 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 42 of U.S. Patent No. 6,080,398.

The instant invention is directed to a pharmaceutical composition for the treatment viral, fungal and bacterial infections using a modified chemokine consisting of amino acids 5-73 of SEQ ID No.3. U.S. Patent No. 6,080,398 teaches a pharmaceutical composition of modified chemokine consisting of amino acids 5-73 of SEQ ID No.3 or a biologically active variant. The broad claims generically read on the instant invention, though the patent does not explicitly recite the modified chemokine consisting of amino acids 5-73 of SEQ ID No.3 for the use in pharmaceutical compositions for treating viral, fungal and bacterial infections. Thus, claim 36 of the instant application is obvious over claim 42 of U.S. Patent No. 6,080,398

7. No claims are allowable.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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June 26, 2001

JEFFREY STUCKER
PRIMARY EXAMINER